Skylife™ Infant Phototherapy System

Service Manual

Service Manual English
500050 Rev A

Caution: Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).

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User Responsibility

Skylife will perform in conformity with the description contained in the instructions for use, service manual, and accompanying labels and/or guides, when assembled, operated, maintained, and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. Should such repair or replacement become necessary, NeoLight recommends making a service request by contacting Customer Service. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by NeoLight and by NeoLight trained personnel. The Product must not be altered without NeoLight's prior written approval. NeoLight LLC is not responsible for any damages or consequences resulting from unauthorized attempts to open, modify, or repair the device. This unauthorized service of the Product also voids the warranty.

The user of this product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than NeoLight. The user is also responsible for ensuring the manual version they reference is the most up-to-date and that the instructions and requirements are followed. Service Maintenance can only be performed by a Biomed technician or other medical professional. The components of the Skylife System must be replaced as directed for the proper function of the system. **Please complete service checks listed in Appendix A every half a year (6 months) to ensure all components of the Skylife device are correctly functioning, and replacements are made accordingly.**

CAUTION:
U.S. Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

Chapter 1: About this Manual

1.1 Indications for Use

Skylife is intended for the treatment of neonatal unconjugated hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath the baby. Skylife must be used within a patient enclosure, such as a bassinet, an open crib, a warming table, or an incubator. Skylife can be used in a clinical setting or in the home.

1.2 Intended Users

This device should only be operated by health care providers or others designated by health care providers* who are trained in its operation and familiar with the risks of this type of device.

1.3 Purpose

The service manual provides a complete guide on troubleshooting and maintaining the Skylife Infant Phototherapy System.

1.4 Product Description

Skylife is a portable phototherapy light system that delivers a narrow band of high-intensity blue light via blue light-emitting diodes (LEDs) to provide treatment for neonatal unconjugated hyperbilirubinemia. Skylife is designed to provide phototherapy treatment from underneath the baby. The system must be used within a patient enclosure, such as a bassinet, an open crib, a warming table, or an incubator.

Skylife utilizes blue LEDs to achieve intensities from 25 $\mu W/cm^2/nm$ to > 55 $\mu W/cm^2/nm$, emitting light in a narrow bandwidth between 430-475 nm. This light bandwidth corresponds to the spectral absorption of light by bilirubin. SkylifeTM utilizes blue LEDs in this range to achieve peak intensities between 25 to 35, 35 to 55, and over 55 $\mu W/cm^2/nm$ at Low, High, and Very High settings. Skylife at the Very High setting provides an average intensity of 56.3 $\mu W/cm^2/nm$ over the treatment area with a peak at 72.4 $\mu W/cm^2/nm$.

Treatment is intended to be applied until the bilirubin levels have dropped sufficiently that the child no longer has jaundice as determined by the attending physician. Phototherapy treatment of neonatal jaundice using Skylife can be applied at home or in a hospital.

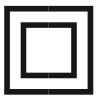
* Such as those using the product through DME groups

Chapter 2: Safety Information

2.1 Symbols

The following symbols are used in this Service Manual, on the device packaging, on the device, and accessory labeling.

Symbol	Description
	Reference Number; Part Number
	Catalog Identification
	Lot Number
	Serial Number
	Manufacturing Date
	Legal Manufacturer Name
	Follow Instructions for Use
	Prescription-only (USA)
	The product contains electrical equipment. Therefore, users should not discard this product along with other household waste.
	Minimum and maximum operating and storage temperature range
	Minimum and maximum storage humidity range
	Minimum and maximum operating atmospheric pressure range.
	Type B.F. Applied parts

	Symbol placed next to **CAUTION** or **WARNING** to alert the users to important statements.
IP23	Protected Electrical shock from touch by hands greater than 12 millimeters. Protection from water sprays less than 60 degrees from vertical.
	Keep the device away from sunlight.
	Keep the device dry.
	Cover patient's eyes during phototherapy.
	Single-use only. Do not reuse.
	Hazard of severe electric shock or burn
	Non Sterile
	Class II Equipment
WARNING	A **WARNING** statement is used when the possibility of injury exists.
CAUTION	A **CAUTION** statement is used when the possibility of damage to the equipment exists.
IMPORTANT!	Instruction provided to help ensure correct clinical results and provide quality assurance to the phototherapy procedures.
NOTE	Background information provided to clarify a particular step or procedure. Information in this category is not considered precautionary

2.2 Warnings

It is important to know and understand the safety measure before using the phototherapy device. The precautions mentioned below prevent possible risk of injury to the patient or the operator and ensure correct equipment usage.

	**WARNING:** Use the Skylife Phototherapy System only for its intended use as described in this manual
	**WARNING:** Never operate the system if it has a damaged plug, damaged or frayed power cord, or wires. Do not insert anything into the end of the plug.
	**WARNING:** Always use the Skylife system in a crib, bassinet, incubator, or warmer where walls protect the baby from injury.
	**WARNING:** Do not use the device in the presence of flammable substances such as anesthetics, cleaning agents, or gases that support combustion.
	**WARNING:** Keep the Skylife controller in a location that is inaccessible to the baby.
	**WARNING:** Keep the Skylife controller and cords in a location away from toddlers, children, or pets.
	**WARNING:** The Skylife Light Bed and GelMat must be used only with the Skylife Disposable Swaddles. Any other type of cover may cause a reduction in light intensity.
	**WARNING:** Baby eye protection is required before turning on the Skylife unit.
	**WARNING:** If the user should experience discomfort from exposure to blue LED light, eye protection is recommended (yellow lenses) while operating the unit.
	**WARNING:** The baby should be wearing only a diaper and not otherwise wrapped or clothed during a treatment.
	**WARNING:** Ensure baby is secured during treatment.
	**WARNING:** Ensure that device cords and other equipment cords are outside the treatment area and do not pose an entanglement, strangulation, or tripping hazard.
	**WARNING:** Do not use the device while bathing or feeding the baby.
	**WARNING:** During phototherapy, the baby's water balance may become disturbed. Therefore, before and during treatment, ensure the baby is adequately hydrated and that their body temperature is maintained.

	**WARNING:** Monitor the baby's bilirubin levels during phototherapy according to your practitioner's recommendations.
	**WARNING:** The Skylife device should be turned off before evaluating the baby's skin color, as lighting will affect visual color evaluation. Parents should contact their medical practitioner if needed.
	**WARNING:** Due to photo effects, drugs should not be stored in the treatment area.
	**WARNING:** Do not use the Skylife system without GelMat and Skylife Disposable Swaddles, or place baby directly on the Light Bed.
	**WARNING:** Always ensure to firmly secure the neonate's arms, legs, and body using the Cloud Swaddle Plus.
	**CAUTION**: Always connect the device to a properly grounded outlet. Do not use an extension cord.
	**CAUTION:** Avoid using the device adjacent to or stacked on other equipment (except incubators, warmers, bassinets, or crib) as it could result in improper operation.
	**CAUTION** Do not disassemble the Skylife device unless you are a certified technician following NeoLight service instructions.
	**CAUTION** Do not use items such as blankets to cover the device.
	**CAUTION**: Do not place the device where it can fall or be pulled into a tub, sink, or other liquid sources.
	**CAUTION**: Do not operate the Skylife unit in temperatures above 37°C (98.6°F). Keep the device away from heated surfaces, heaters, and other heat sources (like fireplaces or warming blankets).
	**CAUTION**: Turn off and unplug the unit during device servicing.
	**CAUTION**: If the Light Bed is exposed to liquid (falling into water or fluid is spilled on the device), immediately unplug the unit from the power source before taking any other action. Discontinue use of the device immediately.
	**CAUTION**: Store the device in a dry location away from direct sunlight. Avoid exposure to dust, lint, or other particulates.
	**CAUTION**: Do not place heavy objects on the Light Bed. This can damage the panel and may affect light output.

CAUTION:
Do not place sharp objects on any device element as it may cause damage.

CAUTION:
Do not drop the device. If the system is dropped, contact your hospital technician or the manufacturer for further information before using the Skylife unit.

CAUTION:
Ensure that the device is inaccessible to children or pets when not in use.

CAUTION:
Handle GelMat with care. Do not stretch, twist, or fold the GelMat.

CAUTION:
Keep sharp objects away from the GelMat

CAUTION:
Do not clean the Light Bed top surface with any liquids. Instead, use dry cloth wipes only on the cloudy area of the Light Bed.

CAUTION:
Not for use with babies greater than 10 kg (22 lbs.).

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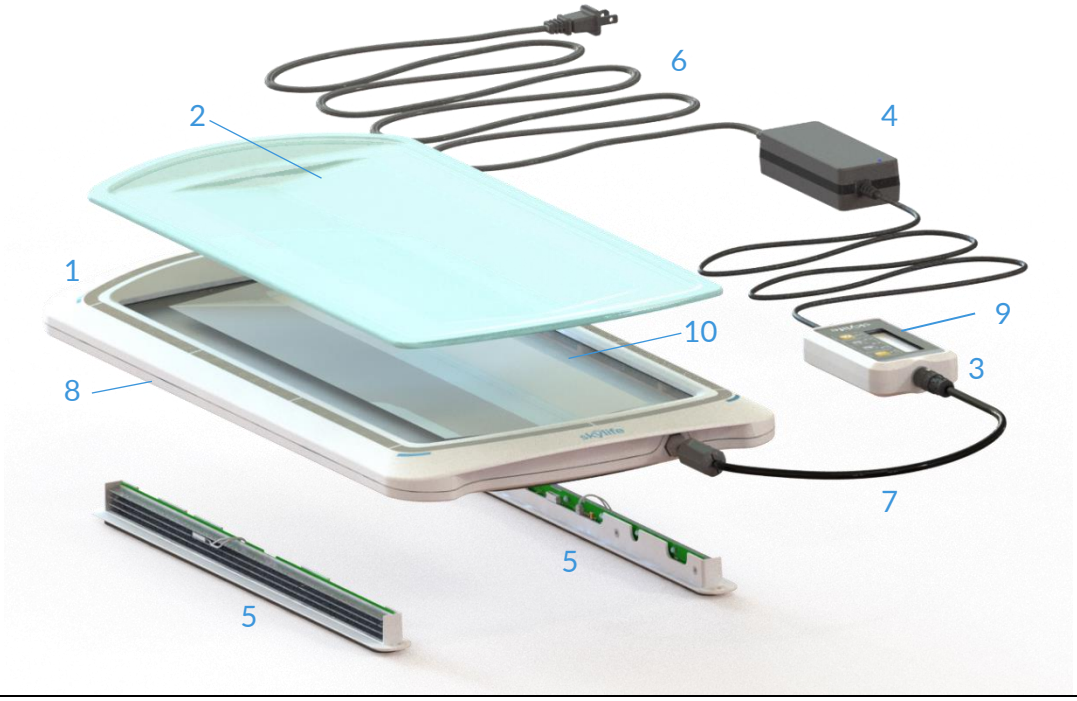
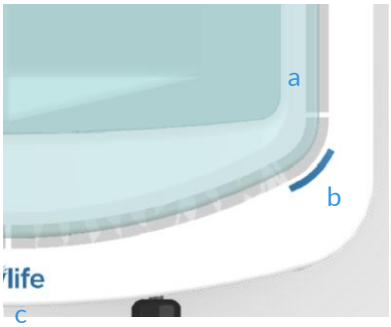
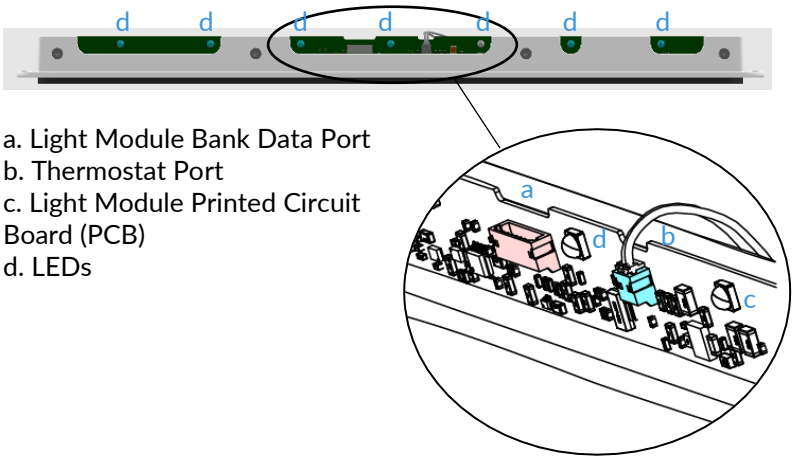
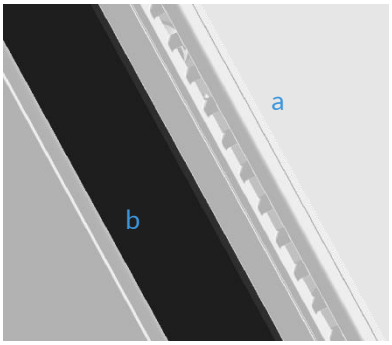
Chapter 3: Components and Controls

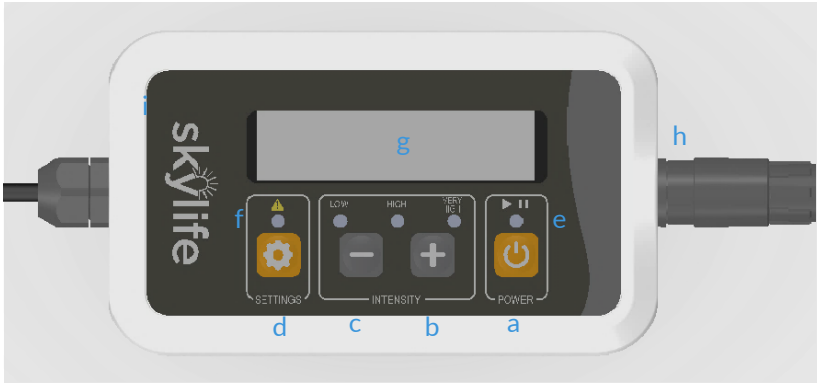
3.1 System Components:



1. Light Bed	The Light Bed is the device's body that houses the light sources and provides a surface to position the patient.  a. GelMat b. GelMat Placement Indicator Stickers c. Handles for Light Bed
2. GelMat	This is a soft transparent gel mattress attached to the top plastic enclosure of the Light Bed. The mattress helps distribute pressure underneath the body prominences of the baby to offer comfort.
3. Controller	The Controller allows the operator to turn the device on/off and set the treatment dosage.
4. AC/DC Adapter	This module converts A.C. power to DC power

5. Light Modules	The two Light Modules house 7 LEDs that provide the therapy  a. Light Module Bank Data Port b. Thermostat Port c. Light Module Printed Circuit Board (PCB) d. LEDs
6. Power Cord	This cord plugs into the electrical outlet
7. Power and Data Cable	This cable connects the Controller and the Light Bed. It carries power and data signals to operate the device.
8. Vent Holes	 a. Provide ventilation for the thermal management of the Light Modules b. Feet to elevate the Light Bed

9. Keypad	The Keypad mounted on the Controller has buttons that allow the device the turn on/off and adjust treatment dosage



a. On/Off Button
b. Increase Light Intensity
c. Decrease Light Intensity
d. Access to System Settings
e. Power Indicator light
f. Warning Indicator light
g. Treatment setting Indicator
h. LCD Display
i. Removable Controller connector

10. Diffuser	Channels the LED light to create a uniform Treatment / Effective Surface Area. It's located beneath the GelMat.
11. Skylife Disposable Swaddle: CloudCover	A disposable product that fits the Light Bed isolates it from the neonate.

12. Skylife Disposable Swaddle: CloudCover Plus	A disposable product that fits on the Light Bed firmly holds the neonate.

Note: Velcro is highlighted in Blue only visualization purposes. The fully engaged CloudCover Plus is shown below.

13. Skylife Carrying Case	High-density plastic case with foam inserts to carry Skylife conveniently for administering Home Phototherapy

14. Skylife Travel Case	High-density plastic case with foam inserts, rollers, and telescopic handles to carry Skylife safely and conveniently for administering Home Phototherapy. The case also comes with a TSA approved padlock

Chapter 4: Routine Maintenance Procedures

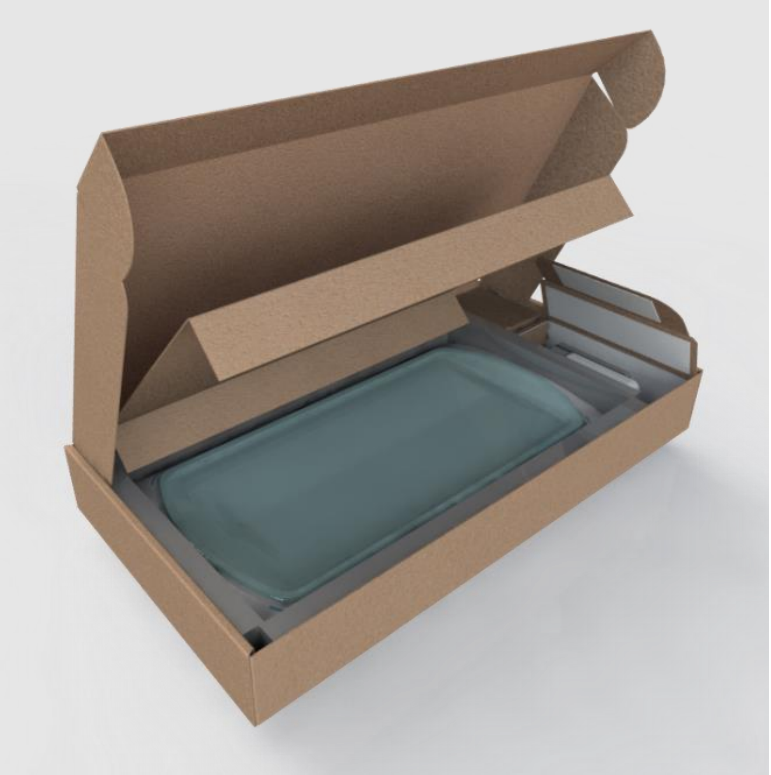
This chapter includes procedures for routine maintenance of the Skylife system. These procedures may be performed after any of the following events and/or as prescribed by the institution's maintenance schedule:

- Initial receipt of the Skylife at the institution.
- Skylife has been visually damaged or subjected to mechanical shock (e.g., dropped).
- Skylife has been submitted for maintenance or scheduled performance verification.

IMPORTANT!	Routine maintenance should be performed according to each section's requirements. Cleaning and disinfection should occur between patients or if the Skylife Disposable Swaddles are soiled or damaged.
IMPORTANT!	The routine maintenance must be performed at the time of replacing the GelMat every 6 months, 1,500 hours of use, or if damaged, whichever comes first
NOTE:	Please record the Light Module hours of use in our Service Guide in Appendices A & B, when the GelMat is replaced. Also, please follow the instructions for each section closely to prevent damage or harm.

4.1 Unpacking and Packing Skylife

1. Skylife is shipped in the following shown packaging schema. Please save all the boxes after unpacking for future shipment of Skylife for possible service and repair activity.

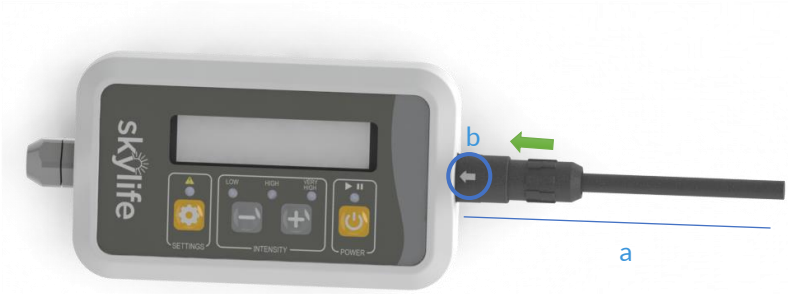


2. Unpack the device and place it on an uncluttered and non-abrasive surface or inside a four-walled enclosure for treatment

3. Connect the Controller and Light bed Power and Data Cable.

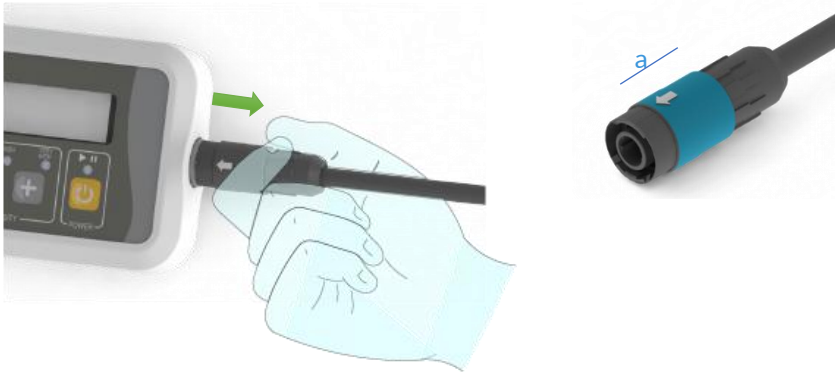
   a: Light Bed Cable

   b: Ensure the Arrow is facing up when connecting



IMPORTANT!
When disconnecting, pull the sleeve to properly disconnect the cable from the port to avoid damaging the connection lock.

a: Sleeve



IMPORTANT!
Disconnect the Controller from the Light Bed only when the device has to be packaged for shipment.

Place the disposable on the device. Hold the ends of a longer edge and slide the distal end beneath the device as shown. Using the Skylife to secure the distal end, pull the proximal end and slide it beneath the device.




NOTE: Ensure that the disposables do not cover the vents

4. Connect the power cord to the electrical outlet

5. Using the Controller, ensure that Skylife can be turned on/off, the light intensity can be increased/decreased, and the treatment can be paused/un-paused.

WARNING!
During this procedure, ensure that the Controller beeps for each button press. Contact NeoLight if the Controller does not provide this audible feedback.

4.2 Cleaning and Disinfection Procedure (for both professional and home use):

It is recommended to use **Super Sani-Cloth®**; however, similar quaternary ammonium disinfectants can be used provided they have similar Isopropyl Alcohol concentration around 55%, Quaternary ammonium compounds concentration of 0.25%, and n-Alkyl Dimethyl Benzyl Ammonium Chloride concentration around 0.25%.

CAUTION:
Unplug the device. Always turn off and disconnect the device from the power outlet before cleaning.

CAUTION:
Skylife consists of the Lightbed with a controller, GelMat, Skylife Disposable Swaddles, and the Power Supply. Only the Light Bed, GelMat, and Power Supply are designed to be reused.

CAUTION:
The Skylife Disposable Swaddles protect the GelMat, and Light Bed from contamination during use. If bodily fluids soak through the Skylife Disposable Swaddles to the GelMat, the GelMat may require cleaning**. Do not remove the GelMat during cleaning.**

CAUTION:
Do not immerse the Skylife or its accessories in liquid or clean with caustic or abrasive cleaners. Likewise, do not spray or pour any liquid on the Skylife enclosure.

CAUTION:
Do not use iodine solutions, strongly acidic or alkaline solutions, and do not autoclave or gas sterilize the Skylife system.

1. Remove the Skylife Disposable Swaddles from the device and discard. Skylife Disposable Swaddles must be discarded between patients, if soiled or after 24 hours of use, whichever comes first.

   Note: If you are using a single-patient-use Skylife mattress cover instead of Skylife Disposable Swaddles, refer to its reprocessing instructions

2. Using recommended, pre-moistened disinfection wipes (such as Super Sani Cloth), remove all visible contamination from the GelMat and verify under standard lighting.

3. After all visible contamination has been removed, use disinfection wipes to thoroughly wet the exposed surfaces of the GelMat and edges of the Light Bed.

4. Ensure that the surface remains visibly wet for 3 minutes at room temperature (68°F/ 20°C) or as specified by product instructions. Use additional wipes as needed to maintain a visibly damp surface.

5. Allow the surface to dry.

6. Follow this by using a clean damp cloth moistened only with clean water to rinse the exposed surfaces. Repeat this at least 2 more times with a clean wet cloth or until any remaining chemical residues are removed.

7. If the device is determined not to be visibly clean after these steps, repeat the cleaning process or do not use the device (refer to section 5 to contact our customer service for further instructions).

4.3 Performance Verification

IMPORTANT! The light output of Skylife was factory calibrated with the Ohmeda Medical BiliBlanket Light Meter ii. Because your facility may use a different Spectroradiometer to measure light intensity output, it is necessary to understand how your reading correlates to the Ohmeda Medical BiliBlanket Light Meter ii reading. The following table provides a light intensity output conversion chart.

GE Ohmeda BiliBlanket Light Meter ii ($\mu W/cm^2/nm$)	**Natus® neoBLUE® Radiometer** ($\mu W/cm^2/nm$)	**Respironics Joey Dosimeter** ($\mu W/cm^2/nm$)
20.0	18.1	52.7
25.0	22.4	65.8
30.0	26.8	78.9
35.0	31.2	92.0
40.0	35.5	105.1
45.0	39.9	118.2
50.0	44.2	131.3
55.0	48.6	144.4
60.0	52.9	157.5
65.0	57.3	170.6
70.0	61.7	183.7
75.0	66.0	196.9
80.0	70.4	210.0

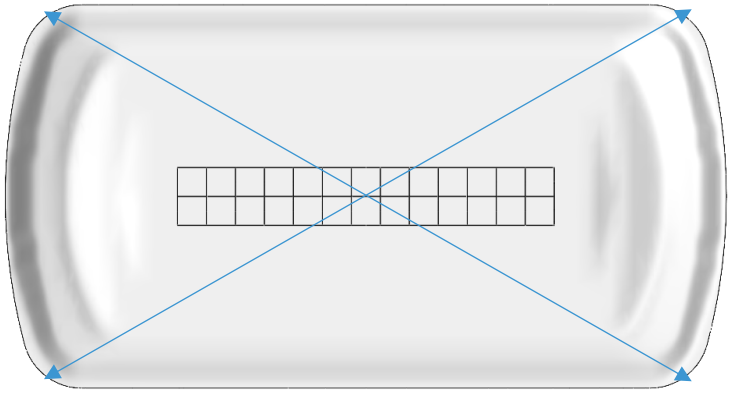
I_{GE}	Conversion Formula: $I_{NN} = 0.8713 * I_{GE} + 0.6617$	Conversion Formula: $I_{RJ} = 2.6214 * I_{GE} + 0.2450$

IMPORTANT! Skylife is factory calibrated with the disposables in place. Therefore, light intensity testing must be performed with a Skylife Disposable Swaddle.

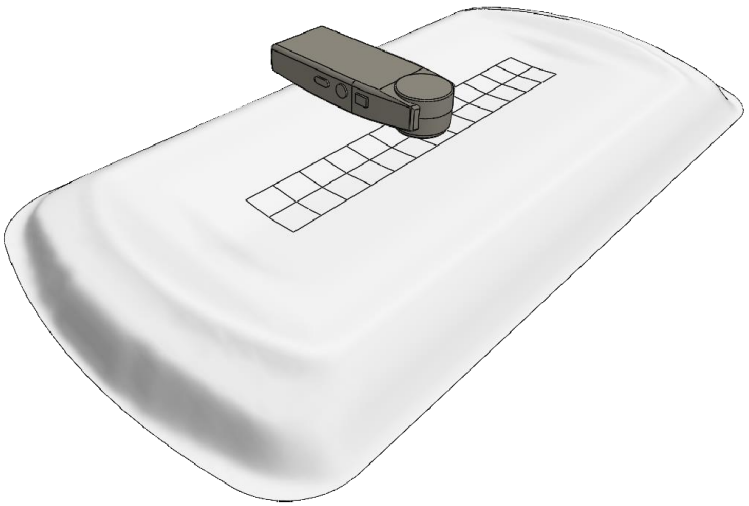
Please ensure Skylife is operating at optimum levels using the following procedure:

1. Skylife's performance is evaluated by measuring its light intensity across twenty-six 1x1" cells at each treatment setting (Low, High, and Very High)

2. Apply a disposable swaddle over the Skylife Light Bed as described in section 4.1. Using a pencil, draw a twenty-six cell grid as shown. Each cell is 1" x 1". Ensure that the 7th cell in both rows is located at the center as shown.



3. Set the treatment setting at the Low. Hold the light meter parallel to the ground, facing Skylife, and line the center of the light meter sensor with the center of a 1x1 cell. Then, *gently press on the swaddle surface until you feel the swaddle fabric's tension*. Then, measure the light intensity at this cell. Repeat the same to collect irradiance measurements from all 26 points on the grid.



NOTE If your facility uses light meters others than GE Ohmeda Biliblanket Mater ii, refer to the table above for conversion or contact customer support.

4. Determine the average of the measurements from the twenty-six locations

$$I_{mean} = \frac{I_1 + I_2 + \ldots + I_{26}}{26}$$

5. Repeat steps 3 and 4 for the High and the Very High setting

6. Add the following offsets to the respective mean values to determine adjusted mean values

Treatment Setting	Offset (δ)
Low Setting	-2.6
High Setting	-3.8
Very High Setting	-5.7

$$I_{mean\_adusted} = I_{mean} + \delta$$

7. Compare the adjusted mean values against the specification.

Treatment Setting	Performance Specification	Acceptance Criteria
Low Setting	$25.0 < I_{mean\_adjusted\_low} \leq 35.0$	Pass
High Setting	$35.0 < I_{mean\_adjusted\_high} \leq 55.0$	Pass
Very High Setting	$55.0 < I_{mean\_adjusted\_vhigh} \leq 72.4$	Pass

8. Spectral measurements are prone to variation in measurement techniques. If the device fails to meet the requirements a 2nd time, contact NeoLight customer support.

4.4 Replacing the GelMat

CAUTION:
Do not clean the Light Bed top surface with any liquids. Instead, use dry cloth wipes only on the cloudy area of the Light Bed.

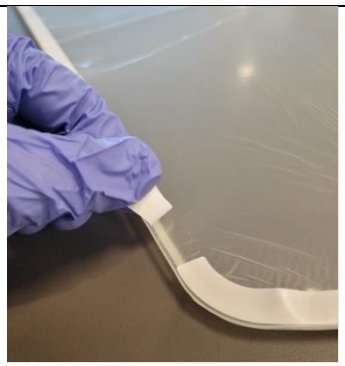
Tools and Materials Required
1. 70% Iso Propyl Alcohol
2. Microfiber cloth

NOTE GelMat should only be replaced by a Biomed technician or other medical professional. Please document this replacement in the Service Guide provided in Appendices A & B.

1. Remove the old GelMat and dispose of it per institutional practices. The GelMat is made from Polyurethane and *cannot* be recycled.

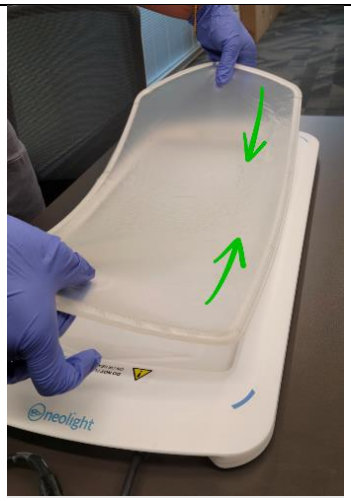
2. Clean the Light Bed plastic surface with 70% Isopropyl Alcohol and a microfiber towel to remove any remaining adhesive residue. Ensure that there is no leftover adhesive or sticky residue before continuing

3. To install the new GelMat, remove the protective liners from the adhesive strips on the back of the GelMat.



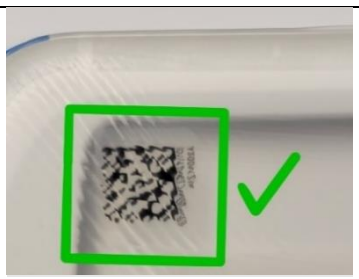
4. To position the GelMat for adhesion, it is recommended to hold the shorter edges with your fingers and place the GelMat down with its center hanging, creating a U-shape.

   Once the position is finalized, gently place the GelMat onto the Light Bed.

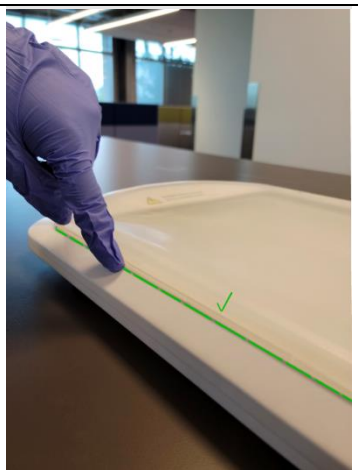


5. Ensure the position of the GelMat is in the center of the Light Bed using the blue lines as indicators.

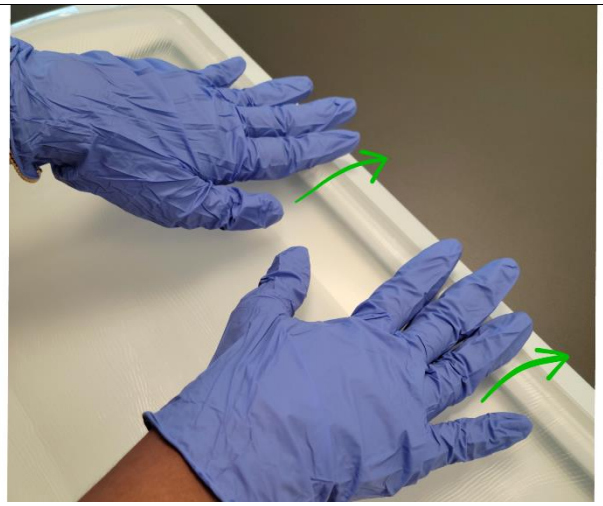
6. Ensure that the GelMat's Q.R. code label does not overlap any of the existing warning labels on the Light Bed.



7. Ensure that the edges of the GelMat align to the edge of the Light Bed and that the corners of the GelMat match the blue line indicators.



8. Starting from the center on one of the long edges, lightly press the GelMat pushing outward to remove any bubbles, continue with the same motion on the other side and then move until all edges have adhered.



9. Firmly press the GelMat onto the Light Bed to finish.

10. Perform a final check by running a finger against the edge of the GelMat to ensure it has securely adhered.

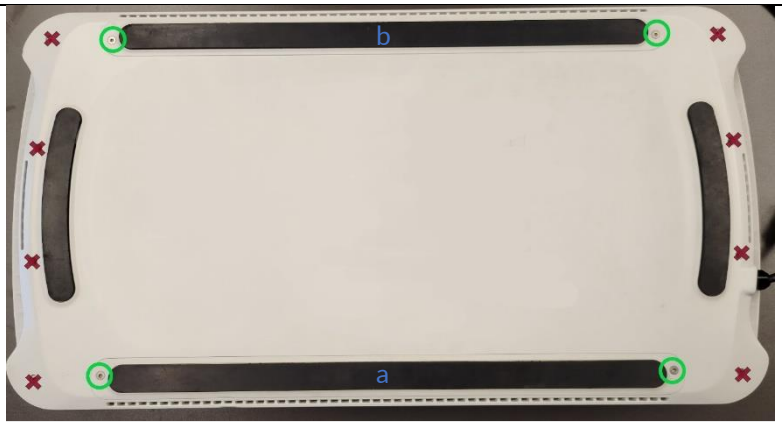
4.5 Replacing Light Modules

Tools and Materials Required
1. Nose pliers
2. 40 in-oz Torque Driver with Torx 10 Tip
3. Tweezers
4. Spare screws - 18-8 Stainless Steel Low-Profile Socket Head Screw with Hex Drive, 6-32 Thread Size, 3/8" Long

CAUTION:
Only use the NeoLight issued light module replacements for the device as any other part may result in the device being ineffective or dangerous to the user.

CAUTION:
Ensure that the device is turned off and unplugged before proceeding.

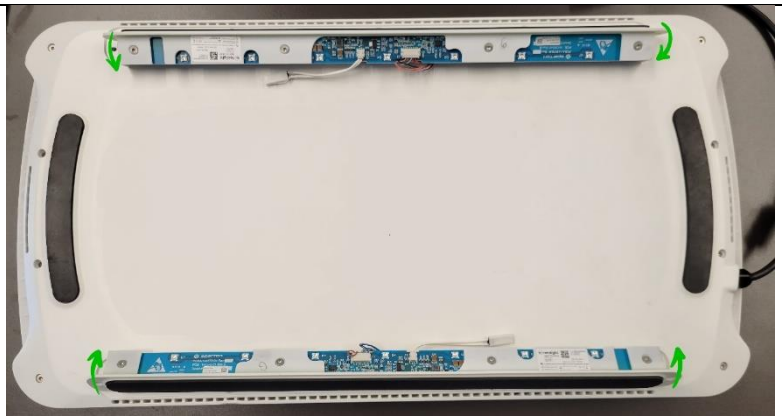
1. Turn the Light Bed upside down. Remove the four screws next to the straight rubber feet, holding the light modules. Do not unscrew the screws shown with the red x marks.



NOTE

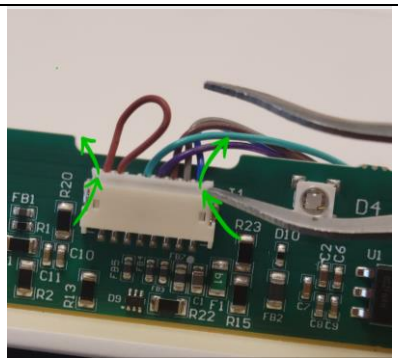
If only one Light Module needs to be replaced, they can be differentiated before removing the screws. Light Module 1 (a) can be accessed with the screws closest to the power and data cable. Therefore Light Module 2 (b) is housed farther from the cable.

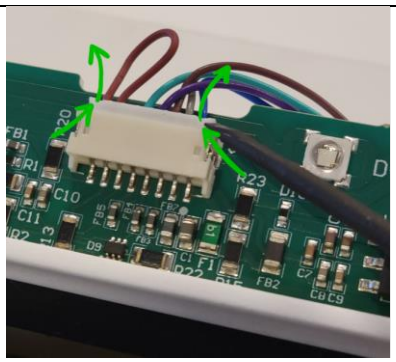
2. Carefully remove the old Light Module from the Light Bed and rest the modules on the Light Bed. Do not strain the connecting wires by placing the Light Modules on the surface you're working on.



3. Carefully remove the Light Module data port by pulling the connector.

   DO NOT pull the wires to disconnect the data port as they may become damaged. Instead, use either tweezers or a small plier to slowly push the connector out, alternating from side to side. Go slow and do not provide too much force as you may damage the board.

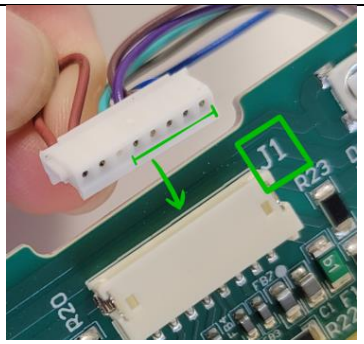


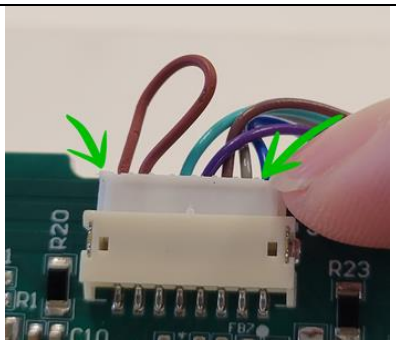


4. Connect the new Light Module data port securely.

   Ensure that the four pins are closest to "J1" for proper connection. Next, push on the edges of the connector with either the same tweezers, flathead screwdriver, or very carefully with the tips of your fingers.

   Make sure to not press on the wires down during this process.





5. Gently place the Light module back into the Light Bed. Tighten the screws to **40 in-oz** by using a calibrated torque screwdriver.

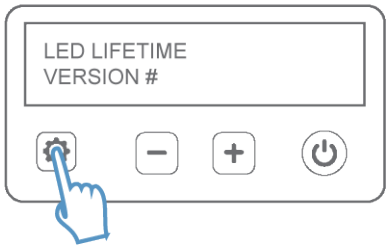
IMPORTANT! Do not over-torque the light module screws as they may damage the device.

4.6 Logging the Light Module Use-life

It is advised to document the Light Module Hours in the provided Service Guide whenever a maintenance check occurs. To check the hours:

1. Ensure that the Skylife system has been powered on as per operating instructions.
2. Once the device is on, begin a standard treatment by pressing the "+" button. Then pause the treatment by pressing the power button once to prevent eye strain from blue light.

3. Then press on the "gear" button to go to settings



4. Here, you will find the Light Module Hours shown as LM1 and LM2 and the firmware version number.

5. Record LM1 and LM2 in the designated box in the Service Guide

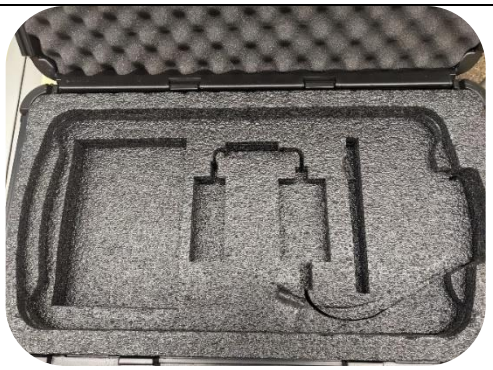
6. You may use the sheet provided Appendices A & B for this purpose. Ensure to start a new sheet after replacing Light Modules.

NOTE	If any errors arise during this process, proceed to **(Troubleshooting Section) * for further instructions.

4.7 Packaging Instructions for Skylife Carrying and Travel Cases

NOTE	This procedure applies to both the Skylife Carrying Case (SKY-CAS) and Skylife travel Case (SKY-TRV)

1. Open out the case on a sufficiently large work surface. Place it so that the long side is facing you.



2. Place the accessories in the slot shown.

3. Fold the power cord half 3 times and use a wire tie to secure it. Then place it in the slot shown.

4. Do not unplug the Controller from the Lightbed. Instead, hold the Power-box and Controller close to each other and fold the cable connecting them in half 2 times. Use a wire tie to secure it

5. Place the assembly into the slot as shown below. Note that the Controller and Lightbed are still connected. Then, start tucking the cable connecting the Lightbed and Controller into the slot as shown. You will have to hold the Lightbed very close to the case while performing this step

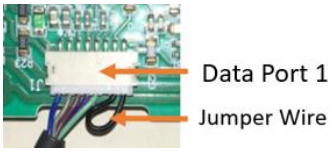
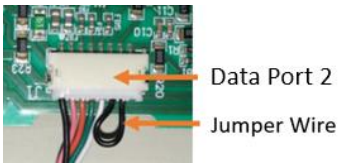
6. Gently place the Skylife unit on the foam as shown, close the lid, and secure with latches/lock.

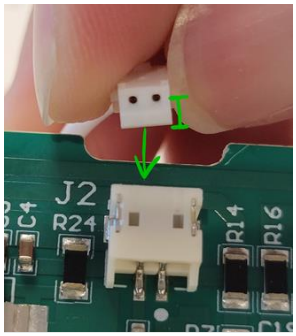
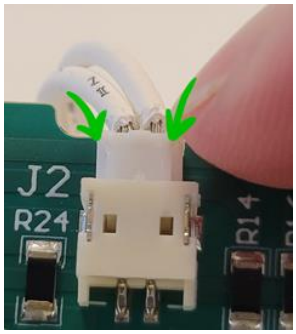
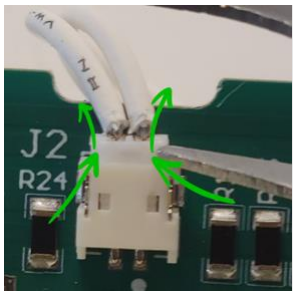
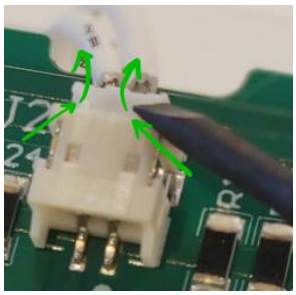
4.8 Homecare Providers

Ensure when you deliver Skylife for use in the home that you provide adequate in-service training for parents or guardians. Be sure to provide all the Instructions for Use, Quick Reference Guides, Skylife Disposable Swaddles, and eye covers.

Chapter 5: Troubleshooting

System Indicators	Likely Cause	Trouble Shooting Steps
Functionality Issues		
- Warning Message: " REPLACE!"	The use-life of the light module is exceeded the recommended limit of 25,000 hours	1. Pressing any key will mute the Warning for 180 seconds 2. Turn-off device 3. Contact NeoLight to order replacement light modules 4. Follow the "Replacing Light Modules" procedure in Chapter 4.5 to replace the old light modules.
- Warning Message: "HIGH TEMP WARNING ANY KEY TO MUTE" - Repetitively beep the buzzer and flash the alarm indicator LEDs.	The LED banks have exceeded the threshold temperature set for Warning	1. Pressing any key will mute the Warning for 180 seconds, but the software shall display a high temp warning. 2. Turn off the device 3. Check if vents are blocked. 4. Clear the area around the device and restart the device after 10 mins. 5. If the issue persists, contact NeoLight.
- Warning Message: "!!HIGH TEMP ALARM TURN DEVICE OFF" - Repetitively beep the buzzer and flash the alarm indicator LEDs. - The treatment indicator LEDs shall turn off	The LED banks have exceeded threshold temperature for Alarms	1. Turn off the device 2. Check if vents are blocked. 3. Clear the area around the device and restart the device after 10 mins. 4. If the issue persists, contact NeoLight. 5. Note: The (+), (+), (-), and settings buttons shall have no action in the Alarm state.
- Warning Message: "POWER INTERRUPTED RESUMING IN xx SEC." - Where xx counts from 10 down to 0, then automatically resumes treatment.	If the system has shut down by unplugging the system from the power supply in the previous session while an active treatment was in progress, or a power outage occurred during treatment.	1. Previous treatment setting is restored in 10 seconds after the restoration of power
- Warning Message: "!! SYSTEM FAILURE 00001"	Controller PCB EEPROM Failure	1. Contact NeoLight.

System Indicators	Likely Cause	Trouble Shooting Steps
Functionality Issues		
- Warning Message: "!! SYSTEM FAILURE 00002"	LED Bank 1 Current Line Failure	1. Follow procedures to open and access the Light Modules in the Replacement instructions in Chapter 4.5. Then, carefully detach Data Port 1 per instructions. 2. Data Port 1 is designed with a jumper wire between **pin 8 and 7** on the cable connector  3. Inspect the connector for sufficient contact. 4. If the connector is not seated correctly, reconnect the bank properly per the provided instructions in Chapter 4.5 and restart the device 5. If wiring damage is seen or if the error persists after correction, contact NeoLight
- Warning Message: "!! SYSTEM FAILURE 00004"	LED Bank 2 Current Line Failure	1. Refer to instructions provided in error **00002** but locate Data Port 2. 2. Data Port 2 is designed with a jumper wire between **pin 6 and 7** on the cable connector 

System Indicators	Likely Cause	Trouble Shooting Steps
Functionality Issues		
- Warning Message: "!! SYSTEM FAILURE 00008"	Bank 1 temperature sensor error	1. Follow procedures in Chapter 4.5 to open and access the Light Modules and follow the procedure to remove Light Bank 1. 2. If the thermostat module is disconnected, reconnect the thermostat and Light Bank, and restart the system. **Important!** Do not press on the wires down during this process.   If the thermostat module was not disconnected, try disconnecting the module using either tweezers or a small flat head screwdriver. Then, reconnect and restart the system.   3. If the wires are damaged or if the issue persists after reconnection, contact NeoLight
- Warning Message: "!! SYSTEM FAILURE 00016"	Bank 2 temperature sensor error	1. Refer to the instructions provided for SYSTEM FAILURE 00008 but access Light Bank 2
- Warning Message: "!! SYSTEM FAILURE 00024"	Bank 1 and Bank 2 Temperature Sensor Error	1. See instructions on how to troubleshoot SYSTEM FAILURE 00004 and SYSTEM FAILURE 00008
- Warning Message: "!! SYSTEM FAILURE 00032"	Bank 1 EEPROM error	1. Restart the system 2. If the error persists, contact NeoLight

System Indicators	Likely Cause	Trouble Shooting Steps
Functionality Issues		
- Warning Message: "!! SYSTEM FAILURE 00064"	Bank 2 EEPROM error	1. Restart the system 2. If the error persists, contact NeoLight
- Warning Message: "!! SYSTEM FAILURE 00120"	Loose Controller J1 Connector	1. Contact NeoLight
- Warning Message: "!! SYSTEM FAILURE 00128"	Stalled Fan	1. Restart the system 2. If the error persists, contact NeoLight
- Warning Message: "!! SYSTEM FAILURE 00256"	Temperature sensor error	1. Turn off the device 2. Check if vents are blocked. 3. Clear the area around the device and restart the device after 10 mins. 4. If the issue persists, contact NeoLight.
Any other error not specified above		1. Contact NeoLight

Damaged Parts		
Cables or Connectors,	1. Incorrect method or excessive force used on attachment and removal of the Controller and Light Bed besides shipping purposes 2. Excess force used when handling cables and device	1. Remove the unit from service and contact NeoLight or trained service personnel. 2. All damaged parts must be replaced and the unit checked to ensure no internal damage has occurred.
Discolored or stained Diffuser	1. Fluid spilled on the Diffuser during GelMat replacement	1. Remove the unit from service and contact NeoLight-authorized and trained service personnel.
Tacky GelMat surface	1. Excessive bending of GelMat can cause delamination and force the encased gel to leak out through the seams 2. A sharp object may have punctured the GelMat exposing the interior gel	1. Replace GelMat
Plastic Enclosure or Diffuser damaged is cracked	1. The unit was dropped or sustained damage through impact with another object.	1. Remove the unit from service and contact NeoLight or trained service personnel. 2. All damaged parts must be replaced and the unit checked to ensure no internal damage has occurred.

Out of Specification		
Light Output measurement is out of specification	1. Improper measurement setup. 2. LED module needs replacing. 3. Aged or worn out GelMat	1. Ensure that the GelMat and one of the disposables are appropriately applied 2. Check if the GelMat has been used for more than 1,500 hrs. If, so please replace GelMat. 3. Make sure to use Ohmeda Medical BiliBlanket Light Meter ii or the meters listed in the conversion table to check light intensity. 4. Repeat the Performance Verification steps to confirm. Also, make sure to hold the meter parallel to the surface and ever so slightly touch the surface of the disposable while taking measurements 5. If the light output is still out of specification, remove the unit from service and contact NeoLight or trained service personnel.

Chapter 6: Accessories and Replacement Parts

Please contact NeoLight customer Service for any replacements and parts needed. The following parts are critical components to the efficacy and safety of our products and must be replaced as directed.

Part Name	Catalog Number	Recommended Replacement Time
Skylife Controller Replacement	SKY-CON	When Controller is damaged and unusable.
Skylife Power Cord US	NL-SK-1-10A	When Controller is damaged and unusable.
LED Light Modules (Pair)	SKY-LIM	25,000 hours of use as indicated in the controller settings.
GelMat (Pack of 1)	SKY-GEL	Every 1,500 hours of use, every 6 calendar months, if damaged, or if the Light Intensity becomes reduced below the calibrated levels, whichever occurs first.
CloudCover	CC-1 (single unit) CC-5 (5 pack)	24 hours of use, if soiled, or between each patient.
CloudCover Plus	CCP-1 (single unit) CCP-5 (5 pack)	24 hours of use, if soiled, or between each patient.
Newborn Eye Protection	NL-EP-01-NEWBORN1	Per patient or if soiled
Preemie Eye Protection	NL-EP-01-PREMIE	Per patient or if soiled
Micro Eye Protection	NL-EP-01-MICRO	Per patient or if soiled
Skylife Carrying Case	SKY-CAS	As required
Skylife Carrying Case	SKY-TRV	As required

The use of non-NeoLight accessories with the Skylife System may reduce treatment efficacy. NeoLight LLC declines all responsibilities for any damages or consequences resulting in using unauthorized parts with our Skylife System.

WARNING!
The use of accessories, replacement parts, or power cords other than those specified by the manufacturer may affect the unit's performance. It could damage the unit or unsafe conditions for the patient and the operator.

Chapter 7: Product Specification

Electrical	
AC Power:	90-264 VAC, 50-60 Hz, 1.0A/115V – 0.5A/230V
Type of Protection against Electrical Shock:	Class II Equipment
Degree of Protection against Electrical Shock:	Type B.F. Applied Part
Degree of Protection against Ingress of Water:	IP23
Mode of Operation:	Continuous
Physical	
Device Dimensions	23.94” L x 12.25” W x 1.91” H (60.81 x 31.12 x 4.85 cm)
Device Weight	< 11 lbs. (5 Kg)
Patient Area	21.41” L x 10.24” W (54.38 x 26 cm)
Effective Surface Area	119in2 (769 cm2)
Light Distribution Ratio (min to max)	>0.4 (avg. 0.79)
Controller Dimensions	4.75” L x 2.75” W x 0.89” H (12.07 x 7 x 2.26 cm)
Controller Weight	<0.5 lb. (0.23 Kg)
Length of device cord to Controller	20" (50.8 cm)
Length of connecting cord between controller and power adapter	53" (134.62 cm)
Length of the power cord from the adapter to plug	66.5" (168.91 cm)
Transportation and Storage	
The Skylife device should be transported and stored in temperatures between -13°F and 122°F (-25°C and 50°C), atmospheric pressures between 50 and 106 kPa (7.25 psi to 15.37 psi) and relative humidity between 10% and 93% R.H.	
Operating Conditions	
The Skylife system should be operated in temperatures between 50°F and 98.6°F (10°C and 37°C), atmospheric pressures between 50 and 106 kPa (7.25psi to 15.3psi), and relative humidity between 15% and 90% R.H.	
Stabilization Time	
The Skylife Phototherapy System does not require a pre-aging time. It is ready for use immediately after turning on the initial time. The Skylife Phototherapy System does not require a stabilization period. It is ready for use immediately after it is powered ON	
Calibration	
No calibration is required to be performed by the user.	

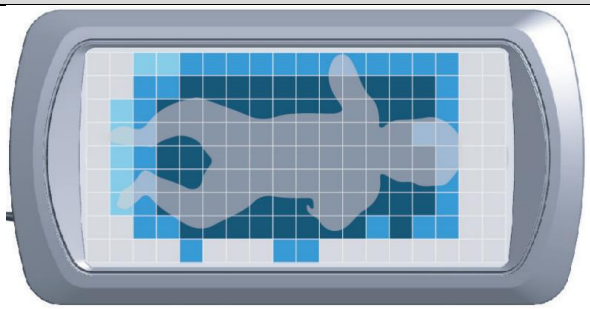
Chapter 8: Technical Reference

Light Distribution

Effective Surface Area is 119 in^2, represented by the blue grid.

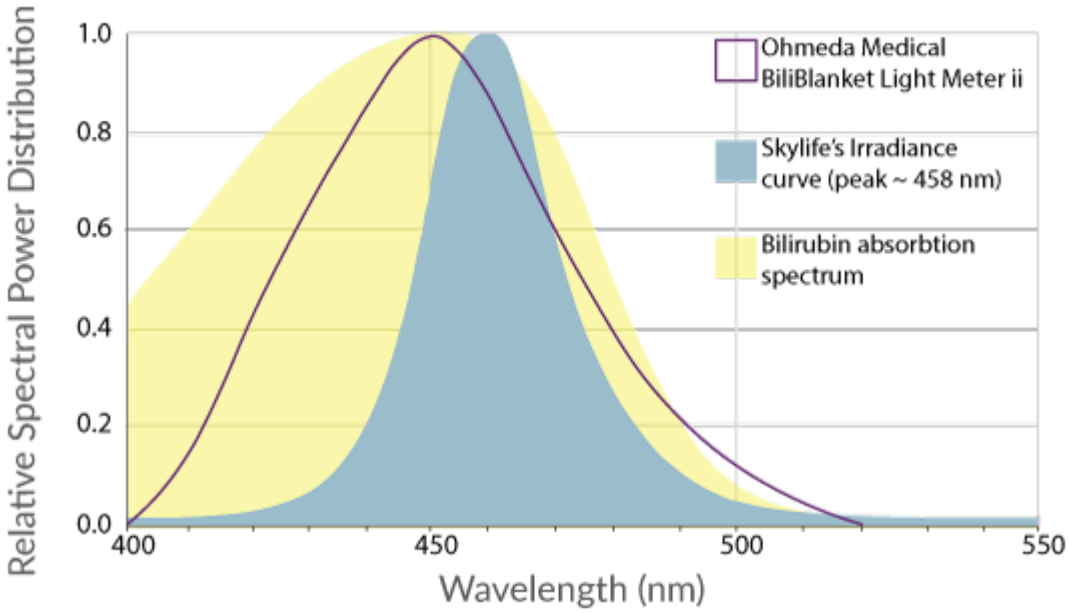
Maximum intensity in the center. The minimum to maximum measured intensity ratio across the effective surface area is >0.4 (avg. 0.79).

Note: The CloudCover attenuates an average of 0.4 $\mu W/cm^2/nm$.



Light Intensity distribution on Lightbed (with GelMat and CloudCover).

Spectral Properties of Light



Chapter 9: Compliance Declaration

IEC 60601-1: 2005, 3rd Edition ANSI/AAMI ED60601-1	Medical Electrical Equipment- Part 1: General Requirements for basic safety and essential performance
IEC 60601-1-2: 2014, 4th Edition	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-6: 2010, 3rd Edition	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability
IEC 60601-1-11:2015	Medical electrical equipment – Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment used in the home healthcare environment
IEC 60601-2-50: 2012, 2nd Edition	Medical electrical equipment – Part 2-50: Particular requirements for the safety of infant phototherapy equipment
IEC 60601-1-8: 2006	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006	Medical device software – Software life cycle processes

Electromagnetic Compatibility (EMC)

The Skylife system is suitable for the electromagnetic environment of typical homes, commercial, or hospital settings. During the immunity testing described below, the Skylife device delivered treatment at a 430-475 nm wavelength at an intensity between 25 to 72 $\mu W/cm^2/nm$.

Warnings

- Portable R.F. communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Skylife device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The Skylife unit should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the device should be observed to verify normal operation. If the operation is not normal, the Skylife device or the other equipment should be relocated.
- The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

Electromagnetic Emissions		
Skylife™ is intended for use in the electromagnetic environment specified below. Therefore, the customer or the user of Skylife™ should ensure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	Skylife™ uses R.F. energy only for its internal function. Therefore, its R.F. emissions are very low and are not likely to cause any interference in nearby electronic equipment.
R.F. emissions CISPR 11	Class B	Skylife™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity		
Skylife™ is intended for use in the electromagnetic environment specified below. Therefore, the customer or the user of Skylife™ should ensure that it is used in such an environment.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	The relative humidity should be at least 5 %
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	The mains power quality should be that of a typical home commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	The mains power quality should be that of a typical home commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	The mains power quality should be that of a typical home commercial or hospital environment. If the user of Skylife™ requires continued operation during power mains interruptions, it is recommended that Skylife™ is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields from common appliances in the home are not expected to affect the device. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Therefore, keep Skylife™ away from sources of high levels of power line magnetic fields (above 30 A/m) to reduce the likelihood of interference."
NOTE: U_T is the A/C mains voltage prior to application of the test level.		

Skylife™ is intended for use in the electromagnetic environment specified below. Therefore, the customer or the device user should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 6 Vrms in ISM and amateur radio bands	Skylife™ is suitable for the electromagnetic environment of typical homes, commercial, or hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

Chapter 10: Warranty

NeoLight, LLC ("NeoLight") warrants to the initial Purchaser ("Purchaser") that each Covered Component of each new Product, as such terms are defined below, purchased hereunder will be free from defects in workmanship and materials for the applicable period of indicated below (each, a "Warranty Period") from the date of the Product's initial shipment to Purchaser.

- Three years for the Skylife Phototherapy System (the "Product") including all components of the Product, excluding the Disposable Parts (collectively with the Light Modules, the "Covered Components").

The GelMat, the Skylife Disposable Swaddles, or other expendable or disposable parts of the Product are the "Disposable Parts."

NeoLight will replace your Skylife device free of charge, provided the system:

- Has been used for its intended purpose by the original owner and in the manner described in this manual.
- Has regular periodic maintenance and service and disposable parts are replaced, and repairs are made according to the service or user manual.
- Has not been connected to an unsuitable power source.
- Has not been subjected to misuse.
- Has not been modified or repaired by any unauthorized party without prior consent from NeoLight.

**Actual results may vary*

Such warranties are extended only with respect to the first purchase of the Skylife Phototherapy System directly from NeoLight or NeoLight's authorized dealers as new merchandise and are extended to the Purchaser thereof; such warranties do not apply to any resale of the Product.

Customer Service:

Please contact Customer Service if you need assistance setting up, using, or maintaining your Skylife Unit(s) or to report any unexpected operation or events. NeoLight Customer Service can be reached at:

support@theNeoLight.com

Customer Support: + 1-866-934-8945 x 1
Technical Support: + 1-866-934-8945 x 2

When returning any products, please include your name, address, phone number, and Return Material Authorization (RMA) number provided by Customer Service. All product returns should be mailed to:

Appendix A: Service Guide - System Evaluation

Lot/Serial #		**Date**	
Controller Evaluation:			
Controller Serial #			

Step	**Criteria**	**Pass**	**Fail**
1	The Controller performs as per instructions in the User Manual		
2	Light Module Use is <24,900 hrs.		

Record Light Module Hours:	**LM1: _____(hrs.) LM2: _____(hrs.)**
Light Bed Evaluation:	
Light Bed Serial #	

Step	**Criteria**	**Pass**	**Fail**
1	GelMat is clear and not yellow/discolored		
2	GelMat is adhered to the Light Bed and not damaged (tears or holes)		
3	GelMat is no older than 6 months, has not undergone more than 1,500 treatment hours, or does not affect calibrated light intensity levels.		
4	All the measured, averaged, and adjusted light intensities per section 4.3 pass the acceptance criteria		

Service Performed/Notes:

Appendix B: Service Guide - GelMat and Light Module Use-life Log

Light Bed S/N: _____ **Controller S/N:** _____

Routine Maintenance / GelMat Replacement #	Expected GelMat Replacement Schedule (Light Module use life in Hours)*	Date	Light Module 1 Life (hours)	Light Module 2 Life (hours)
1	1,500			
2	3,000			
3	4,500			
4	6,000			
5	7,500			
6	9,000			
7	10,500			
8	12,000			
9	13,500			
10	15,000			
11	16,500			
12	18,000			
13	19,500			
14	21,000			
15	22,500			
16	24,000			
17	25,000			

IMPORTANT! The routine maintenance must be performed at the time of replacing the GelMat every 6 months, 1,500 hours of use, or if damaged, whichever comes first